EXHIBIT 1

AMERICAN ARBITRATION ASSOCIATION
NEW YORK, NEW YORK

ACORDA THERAPEUTICS, INC., Claimant, v. ALKERMES PLC, Respondent.	)	Case No. 01-20-0010-8421 CONFIDENTIAL

ALKERMES'S PRE-HEARING MEMORANDUM

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I. INTRODUCTION

Following the Panel's summary judgment rulings, only a few narrow issues remain to be decided at the Hearing. Acorda's sole remaining claim for monetary relief is for a refund of some or all of the money it paid to Alkermes relating to AMPYRA® starting in July 2020. *See* Order #23. That claim hinges on Acorda's ability to prove a *Brulotte* violation, among other things. The Panel entered judgment for Alkermes on all of Acorda's claims for lost profits, and for recovery of any money Acorda paid to Alkermes prior to its first payment under protest in July 2020, meaning Acorda has no other claim for monetary relief left. Alkermes will show at the Hearing Acorda is not entitled to any recovery whatsoever. But even if the Panel were to disagree and find a *Brulotte* violation, any award to Acorda should be no more than $6.5 million, as explained below.

For the same reasons, Acorda's requests for declaratory relief should be rejected. With no basis for finding a *Brulotte* violation, there is equally no basis for an order lowering Acorda's future payments to Alkermes. But again, even if the Panel were to find a *Brulotte* violation, the Panel should order that the Elan Royalty rate going forward is reduced to no less than the 4.25% figure set out in Article 5.6.2 of the License Agreement ("LA"). There is no basis to order any change to the Supply Agreement ("SA"), including the Supply Price.

II. BACKGROUND

The LA remains in effect and will run at least until September 2023. The earliest the agreement could otherwise have terminated was September 26, 2018, but it also permitted the parties to agree to extend that term for five-year periods. *See* LA (J-001), Art. 12.5.1. The parties executed such an extension agreement on a timely basis in 2016, and the five-year extension began upon the end of the initial term, so the agreement remains in effect. J-143. Because the LA remains in effect, so too does the SA. *See* SA (J-002), Cl. 11.1.

The LA explicitly obligates Acorda to continue paying royalties to Alkermes even

when all relevant Alkermes patent rights have expired. Alkermes has licensed to Acorda both Elan Know-How and separately Elan Patent Rights. The running-royalty provisions expressly provide for the payment of know-how royalties when no licensed patent rights remain. Article 5.6.1 states Acorda shall pay royalties "in consideration of the rights and license granted to Acorda of the Elan Know-How" after all Valid Claims have lapsed, and Article 5.6.2 states "Acorda shall pay to [Alkermes] the applicable Elan Royalty" in "countries where there are no Valid Claims." The "duration and termination" provision in Article 12.5 also contemplates Acorda's obligation to pay know-how royalties after Alkermes's patent rights have lapsed. The "Initial Period" ran until the *latest* of three events, one of which was the expiration of all Elan Patent Rights, meaning that if that condition occurred first or second, the LA would remain in place. *See* LA, Art. 12.5.1.1.[1]

Thus, the plain terms of the LA and the extension agreement required Acorda to continue paying royalties to Alkermes from July 2020 (the only payments still in dispute), as the Panel recognized in granting summary judgment dismissing Acorda's claim for breach of contract.

Alkermes's Know-How Has Provided Significant Value to Acorda. While the terms of the agreements requiring ongoing payments are controlling, Acorda's continued obligation to pay royalties to Alkermes makes perfect sense. The Alkermes-Acorda collaboration, which led to the approval and marketing of AMPYRA®, has been extremely profitable for Acorda. None of the relevant financials are disputed. Acorda did not generate a profit until AMPYRA® launched in 2010, 15 years after it was incorporated. From AMPYRA®'s launch in 2010 through generic entry in late 2018, Acorda recorded U.S. net sales for AMPYRA® of approximately $3 billion. Peak annual revenues were almost $600 million, ten times higher than any other Acorda product.

[1] Furthermore, when the LA was executed in September 2003, U.S. Patent No. 5,540,938 ("the '938 Patent") was due to expire in July 2013 while the Initial Period extended to September 2018, showing that the parties intended the LA to continue past the expiration of the '938 Patent.

Following loss of exclusivity ("LOE"), AMPYRA® sales outperformed industry benchmarks, as both sides' experts agree. Those sales also far surpassed Acorda's own forecasts. In November 2018, Acorda management told its board of directors that AMPYRA® sales would fall to $61 million in 2019, $40 million in 2020, and $25 million in 2021, totaling $126 million. In fact, AMPYRA®'s sales in those years were $163.2M, $98.1M, and $84.6M respectively, totaling $346 million, almost three times Acorda's 2018 forecast. R-079 at 28. AMPYRA® retained about 25% of dalfampridine ER sales a year after generic entry and an almost 20% share at the end of 2020.

The evidence will show that Alkermes's propriety know-how was crucial to AMPYRA®'s post-LOE success. Among other witnesses, Alkermes will present testimony from Padraig Glynn, an analytical pharmaceutical scientist, who was directly involved in developing AMPYRA® and the proprietary know-how that Alkermes licensed to Acorda, and from Dr. Walter Chambliss, Professor Emeritus of Pharmaceutics and Drug Delivery at the University of Mississippi. Their testimony will explain how, with the exception of the phase III clinical trials, Alkermes did the entirety of the formulation development work for AMPYRA®, as well as some early clinical studies, and discovered and solved critical issues relating to impurities and tableting parameters necessary for FDA approval and the commercial manufacture of AMPYRA®. They will further explain how this Elan Know-How is reflected in the New Drug Application ("NDA") that FDA approved and constitutes the basis allowing Acorda to continue selling AMPYRA®.

Alkermes also will present testimony from Dr. Sumanth Addanki, an economist with extensive experience in pharmaceutical markets and intellectual property. His testimony will confirm that AMPYRA®'s post-LOE sales exceed industry averages, show how those sales levels must result from Alkermes's know-how because the alternative reasons offered by Acorda cannot explain them, and opine that the incremental profits Acorda has realized by having access to

Alkermes's know-how more than justify the ongoing royalties Acorda has been paying.

Acorda's own documents corroborate the reality that Alkermes's know-how exists and is driving AMPYRA®'s above-average post-LOE success. Acorda represented to FDA in sworn statements that there was critical impurity-related know-how, which FDA accepted and recognized. J-147 at -432. Acorda reported in annual filings to the FDA that numerous patients contacted Acorda to state they had been taking a generic dalfampridine ER product but that it was less effective than the brand, took longer than the brand to work, and then wore off too quickly.[2] Some patients reported generics had inconsistent results *except* when using the Mylan AG, which was manufactured using the Elan Know-How, supporting the contention that the know-how makes AMPYRA® work better than the generics for at least some patients, and patients notice. *See, e.g.*, J-206 at -256, -262. Acorda personnel told Alkermes in March 2019 that, although they had not done studies to prove this hypothesis, "Acorda believe[s] that the generic may give more dose more quickly, but the effect may wear off more quickly vs. the consistent therapeutic blood levels achieved with AMPYRA." J-184. These effects were so prevalent that, as Acorda reported in prep notes for an earnings call, close to 900 patients taking a generic post-LOE returned to branded AMPYRA in Q2 2019 alone. J-269 at -562.

III. ACORDA CANNOT SHOW IT IS ENTITLED TO RELIEF

Acorda, as the claimant, bears the burden of proof in this matter. That burden includes showing (a) that the *Brulotte* doctrine even applies to the Alkermes-Acorda collaboration, which is a strategic alliance far broader than a simple patent license; (b) assuming the *Brulotte* doctrine applies, that the terms of the LA breach that rule; (c) assuming there would be a *Brulotte* violation, that the severability clause in Article 12.4 would not deem the LA amended (by reducing the know-

[2] *See, e.g.*, J-157 at -632, -647, -687, -708, -860; J-206 at -241, -251, -257-58, -270, -278, -362, -364, -434, -439, -460, -627, -751; J-243 at -972, -034, -088, -109, -129, -130, -146, -273-75.

how royalty to no less than 4.25%) to cure the violation and maintain the enforceability of the royalty; (d) that a *Brulotte* violation would have any bearing on the Supply Price payments, which even Acorda admits are not patent royalties; and (e) that Acorda made a proper protest as to the Supply Price payments at the time of payment.

For both legal and factual reasons, Acorda will not be able to carry its burden on any of these topics. The appropriate outcome, therefore, would be for the Panel to reject the remaining claims in Acorda's demand in their entirety. At most, if the Panel were to find a *Brulotte* violation, the Panel should (a) deem that the know-how royalty was amended down to 4.25% per Article 12.4 and Article 5.6.2, which also would be the rate going forward; (b) award Acorda the difference between the royalties it paid under the LA from July 2020 forward calculated as 10% of Net Selling Price ("NSP") and the amount those royalties would have been if calculated as 4.25% of NSP, which would be approximately $6.5 million; and (c) deny any recovery for Supply Price payments.

A. Acorda Cannot Prove a *Brulotte* Violation

Following the Panel's summary judgment opinion, Acorda's only avenue to recover damages is "if Acorda is successful on its *Brulotte* claim[, then] it could also be entitled to recover unjust enrichment/restitution damages" for the period after its first payment under protest in July 2020. Order #23 at 12. For three independent reasons, the evidence here shows that there is no *Brulotte* violation.[3] Each reason, separately and together, compels the entry of judgment in favor of Alkermes on Acorda's only remaining claims.

1. *Brulotte* Does Not Apply to the Alkermes-Acorda Collaboration

Acorda's request for relief under *Brulotte* fails at the first step, because the *Brulotte* doctrine does not apply here. In *Kimble*, the Supreme Court held, in discussing permissible "ways

[3] As Alkermes previously informed the Panel, Alkermes will not argue at the Hearing that continuing Elan Patent Rights defeat Acorda's *Brulotte* claims.

around *Brulotte*, enabling [parties] to achieve those same ends," that "most broadly, *Brulotte* poses no bar to business arrangements other than royalties—all kinds of joint ventures, for example—that enable parties to share the risks and rewards of commercializing an invention." *Kimble v. Marvel Ent., LLC*, 576 U.S. 446, 453-54 (2015). The facts here show that the Acorda-Alkermes collaboration is an example of the type of business arrangement that is outside the scope of the *Brulotte* doctrine, so there can be no violation.

When Acorda and Alkermes first entered into an agreement relating to MS in 1998, they structured their collaboration as a formal joint venture ("JV"), including by creating a new entity ("Newco"). J-011. In 2003, the parties agreed to restructure their agreement, largely in response to pressure Elan was receiving from U.S. regulators in relation to the accounting of revenue from off-balance-sheet JV entities like Newco. J-251. That restructuring led to the 2003 agreements at issue here where the parties unwound the formal JV by dissolving "Newco." *See* LA, Art. 12.7. But the revised business arrangement in the 2003 amended agreements remained a highly collaborative venture with general obligations of each party to contribute to the shared "Project"[4] of developing AMPYRA® and bringing it to market, with Alkermes responsible for product development and supply, and Acorda responsible for clinical trials. Each party committed to the other to "use its reasonable efforts, as would be deemed commensurate with the achievement of its own business aims for a similar product of its own to conduct such part of the Project as the Parties mutually agree shall be conducted by" that Party. LA, Art. 3.1. Per Article 3.3:

> The Parties hereby confirm that each shall undertake its respective part of the Project as a collaborative effort and that the provisions of this Agreement requires [sic] that each Party diligently carries out those tasks assigned to it under the Project and as otherwise agreed during the course of the Project. Each Party shall co-operate with the other in good faith particularly with respect to unknown problems

[4] The LA defines the "Project" in relevant part as "all activity undertaken by Elan and Acorda in order to develop the Product in accordance with the Development Plan, together with … all activity as undertaken by Elan, Acorda and [Newco] to develop the Fampridine Product for MS, prior to the Amendment Date." LA, Art. 1.1.

> or contingencies and shall perform its obligations in good faith and in a commercially reasonable, diligent and workmanlike manner. Each Party will update the other Party on the progress of the Project at meetings of the Committee.

Alkermes contributed far more than a bare patent license to the collaboration. As Mr. Glynn will show, Alkermes's contributions included its proprietary methods of analyzing and manufacturing AMPYRA® that were required for FDA approval, which it spent years developing. And Acorda needed this contribution from Alkermes. Acorda knew that, to address toxicity risks, a dalfampridine product would need to be in an extended-release form to obtain FDA approval and be marketable. But Acorda did not have such a formulation prior to joining forces with Alkermes, nor did it have the capability to invent and develop such a formulation itself; all that the contract manufacturing organizations working with Acorda had developed was an immediate-release formulation. Alkermes provided Acorda not just with its extended-release formulation, but also Alkermes's expertise to develop a commercial product and scaled-up process for its manufacture. All of the pivotal clinical trials conducted to obtain FDA approval for AMPYRA® used the tablet formulation developed by Alkermes. LA, Arts. 3.4, 3.5. Alkermes also supplied the work for the chemistry, manufacturing, and controls ("CMC") section of the AMPYRA® NDA and provided support in addressing CMC questions raised by the FDA. LA, Art. 3.8. Every tablet of AMPYRA® sold in the U.S. was and continues to be made either by Alkermes using its proprietary formulation, or by Patheon, to which Alkermes effectuated an extensive "tech transfer"—under strict confidentiality—as required by the LA so it too could manufacture the product using Alkermes's proprietary formulation, expertise, and know-how. LA, Sched. 9; SA, Cl. 7.1. Acorda is permitted to reference that proprietary work and know-how in the NDA by virtue of its license from Alkermes. In other words, without the CMC section and the other NDA sections provided by Alkermes and containing its know-how, Acorda would not have an NDA, would not have an FDA-approved tablet formulation, and would not be allowed to sell AMPYRA®.

The LA established a "Committee" comprised of three Acorda employees and three Alkermes employees, charged "to provide oversight, review and coordination relating to the development, manufacturing and supply, Regulatory Approval and commercialisation of the Product." LA, Art. 10.1. Alkermes and Acorda coordinated development activities and regularly met to develop a strategy for FDA approval and commercialization. The Committee also was responsible for, among other things, "facilitating the transfer of know-how . . . as contemplated by this Agreement and the Supply Agreement." LA, Art. 10.2.2. Dr. Richie Paul will testify about how the Committee works. Prior to AMPYRA®'s approval, the Committee would discuss the progress of development and regulatory updates. After AMPYRA®'s approval, Acorda would provide updates on marketing and sales, and Alkermes would provide updates on manufacturing and supply, transfer of know-how, regulatory compliance and quality control issues. The Committee is still in place to this day, meeting bi-annually to transact its business.

Alkermes assumed considerable risk in connection with this collaboration. The licenses Alkermes granted to Acorda were exclusive (*see* LA, Art. 2.8), and Alkermes agreed in the SA not to manufacture or supply its proprietary formulation to anyone else (*see* SA, Cl. 2.2). Therefore, even though Alkermes had done all the product development work itself, the only way Alkermes could obtain value from that work was through its collaboration with Acorda. If Acorda failed to develop a marketable product, Alkermes would not reap any benefit from its work. But if the venture succeeded, Alkermes would share in the upside through the royalties under the LA and, separately, the profits on manufacture under the SA. Thus, Acorda and Alkermes both had significant financial stakes in the common undertaking of developing and marketing AMPYRA®.

This and other evidence confirms that the highly collaborative Alkermes-Acorda business structure comprises far more than a bare license agreement. The evidence will show that the

companies have been engaged in a strategic alliance that enabled the parties to share in the risks and rewards of development and commercialization of dalfampridine. From this evidence, the Panel should conclude that the Alkermes-Acorda collaboration is a type of business arrangement that, per *Kimble*, is not subject to *Brulotte*, and thus that Acorda will have failed to show a *Brulotte* violation. On its own, that will require judgment for Alkermes on all remaining claims.

2. **Even if *Brulotte* Applies, There Is No Violation**

Alternatively, the Panel should find that the structure of the royalties in the LA complies with *Brulotte* and *Kimble* in any event.

a. The Patent Royalty is Greater than the Know-How Royalty

Cases uniformly hold that when an agreement provides that the royalty rate when the licensed patents remain valid is greater than the post-patent rate for non-patent rights (e.g., if there is a step-down), there is "no problem" under *Brulotte*. *Kimble*, 576 U.S. at 454, 459. Here, although the royalty structure is a bit more complex than a simple step-down in the rate for the running royalty, the LA plainly sets out patent royalties that are greater than the know-how royalties. The *patent* royalty under the LA comprises *both* lump-sum royalty payments of approximately $25 million (Arts. 5.2 & 5.3) *and* running royalty payments of 10% of AMPYRA®'s NSP (Art. 5.6.1). In contrast, the know-how royalty is comprised *only* of a 10% running royalty, which is reduced to 4.25% under certain conditions. Arts. 5.6.1 & 5.6.2. The lump-sum patent royalties must be taken into account in the *Brulotte* analysis because lump-sum royalties are often used to "buy down" the percentage rate used in the running royalty component.[5] In other words, the effective patent royalty rate is greater than 10% of NSP; the know-how royalty

[5] *See, e.g., Tr. of Bos. Univ. v. Everlight Elecs. Co., Ltd.*, 2015 WL 6408118, at *2 (D. Mass. Oct. 23, 2015); *Commc'n Tech. Holdings, Ltd. v. Telefonaktiebolaget LM Ericsson*, 2018 WL 4488286, at *36 (C.D. Cal. Sept. 14, 2018), *rev'd in part, vacated in part on other grounds*, 943 F.3d 1360 (Fed. Cir. 2019).

rate is not. Acorda therefore cannot show any *Brulotte* violation.

b. Even if the Panel Considers Only the Running-Royalty Rates, There is Still No *Brulotte* Violation

Furthermore, even the use of the 10% running royalty for both the patent and the know-how royalty rates creates "no problem." Acorda operates from the premise that a step-down is always required to comply with *Brulotte*, but the law says otherwise. "[A] discounted rate may not be necessary to avoid *Brulotte* [when there is] some other clear indication that the royalty [due after patent expiry] was in no way subject to patent leverage." *Kimble v. Marvel Enters.*, 727 F.3d 856, 865 (9th Cir. 2013). As the Ninth Circuit explained, "had the parties explicitly indicated, in a separate section of the agreement, that royalty payments for sales of non-patented products . . . were to be paid [for know-how], it would arguably be immaterial if the rate were the same as the rate for sales of allegedly patent-infringing products." *Id.* at 865 n.5. Nothing in the Supreme Court's *Kimble* decision holds otherwise, and those facts are present here. First, as Alkermes's lead negotiator of the 2003 agreements, Alex Nesbitt, will testify, Alkermes did not have coercive power during the relevant negotiations, supporting that the royalty was not subject to patent leverage. Second, the LA explicitly separates the patent running royalty from the know-how running royalty in two ways: (a) by separately setting out the running royalty rate in Article 5.6.1 for the period *before* patent expiry and *after* expiry when the rate is for know-how; and (b) by comparing 5.6.1 to 5.6.2, which applies when there is no Valid Claim and thus the rate is for know-how alone. These provisions show that the parties separately bargained for and agreed on the know-how only royalty rate. For this reason, too, there is no *Brulotte* violation.

B. The Know-How Royalty Remains Enforceable In Any Event Because, if a *Brulotte* Violation Otherwise Would Occur, the LA Provides that the Royalty Rate is Deemed Amended, Curing any Unenforceability

Even if the Panel were to conclude that the royalty structure as drafted in the LA does not

comply with *Brulotte*, the LA itself contains a mechanism that amends the agreement and cures any potential *Brulotte* violation. In Article 12.4, the LA states in relevant part:

> Severability: If any provision of this Agreement is … deemed to be, or becomes invalid, illegal, void or unenforceable under any law that is applicable hereto, (i) such provision will be deemed amended to conform to applicable laws so as to be valid and enforceable . . . .

By asserting a *Brulotte* violation, Acorda is necessarily arguing that the purported lack of a step-down renders the royalty rate in Article 5.6.1 unenforceable. If the Panel were to agree, then Article 12.4 provides the cure that maintains the enforceability of the know-how royalty: the amount of the know-how royalty "will be deemed amended to conform" with *Brulotte*. This contractual cure would reduce the know-how royalty to no lower than 4.25% of NSP. As a result, the know-how royalty would remain enforceable at the amended rate, and any refund to Acorda would be limited to the difference in rates (10% - 4.25% = 5.75%) for July 2020 forward.

In *Kimble*, the Supreme Court held a step-down from 5% (for a combined patent and trade secret license) to 4% (for a license to the trade secret alone) would fully comply with *Brulotte*. 576 U.S. at 454. Here, if a step-down were required to avoid a *Brulotte* violation, the LA is deemed amended per Article 12.4 so that, after the '938 patent expires, the know-how royalty is 4.25% of NSP. That figure, which is in Article 5.6.2, reflects the parties' agreement as the lowest royalty rate that would apply to know-how. The provision states in relevant part:

> if, and only if, (a) Elan is not manufacturing the Product, (b) there are no Valid Claims covering the Product and (c) there is Competition in any such country, the Elan Royalty due under Article 5.6.1 on Product sales in such country [i.e., 10% of NSP] shall be reduced to four and one-quarter per cent (4.25%) of NSP

These terms make clear that the 4.25% can only be for the know-how license: it cannot be for patent rights (it applies when there are no Valid Claims), and it cannot be for manufacturing (it applies when Alkermes is not manufacturing the Product). And this makes sense: if someone else is manufacturing Product—which is defined in Article 1.1 as a product that "incorporates Elan

Know-How in material part"—that manufacturer by definition is using Alkermes's know-how, and the royalty is for Acorda's continued reliance on that know-how in its NDA and for that third-party's use of Alkermes's know-how in the manufacturing of AMPYRA® for Acorda. The 4.25% also accounts for the presence of "Competition"—that is, the fact that generics have entered and caused AMPYRA®'s market share to fall (*see* LA, Art. 1.1).

Given that the 4.25% rate applies when all three conditions of Article 5.6.2 have been met, it clearly is fully supported when—as here—only two of those three conditions have been met.[6] Thus, if it is necessary to apply Article 12.4 here (which Alkermes disputes as there is no *Brulotte* violation), the process is simple: the post-patent know-how royalty rate in Articles 5.6.1 and/or 5.6.2 is deemed amended to 4.25% of NSP, creating a step-down in the running royalty from 10% to 4.25%, which indisputably complies with *Brulotte* and *Kimble*. At most, Acorda would have a restitution/unjust enrichment claim for the difference between royalty payments under the LA (calculated as 10% of NSP) and the amended rate (4.25%) for the period July 2020 forward, which comes to $6.5 million of the $11.35 million in Elan Royalties that Acorda paid during the period.[7]

C. Acorda Is Not Entitled to Any Refund of Supply Price Payments

No matter how the Panel rules with respect to *Brulotte*, Acorda has no basis to recover any of its Supply Price payments to Alkermes, for several reasons.

First, as a threshold matter, the evidence will show that Acorda did not make a written protest in connection with any of its Supply Price payments. While Acorda started including protest language on its invoices to Alkermes in July 2020, that language was clearly and

[6] For purposes of the Hearing, Alkermes agrees that (a) there are no more Valid Claims, and (b) there was Competition in the U.S. as of 2020; but Alkermes continues to manufacture and supply AMPYRA® to Acorda.

[7] Even if the Panel were to find the royalty unenforceable in its entirety and order a refund, Alkermes would be entitled to equitable restitution for Acorda's use of the Elan Know-How. *See*, *e.g.*, *De Simone v. VSL Pharms., Inc.*, 395 F. Supp. 3d 617, 635–36 (D. Md. 2019); Alk. Waldron *Daubert* Mot. at 5-6 (citing cases). For those purposes, the Elan Know-How would have the same value of at least the 4.25% rate. The net award to Acorda, therefore, would be the same as if the rate were deemed amended under Article 12.4 down to 4.25%.

consistently limited to protesting the 10% royalties under the LA. Not once did the protest language refer to the 8% Supply Price. Thus, Acorda cannot show that it made those payments under protest, as the Panel's Summary Judgment Order requires as a precondition to recovery.

Second, a *Brulotte* violation (even if found) has nothing to do with the 8% Supply Price. *Brulotte*'s reach is limited to preventing the improper extension of *patent royalties*, but has no bearing on non-patent royalties or non-royalty price terms, such as the price for manufactured goods. *Kimble* 576 U.S. at 454, 459 (clarifying *Brulotte* poses no barrier for post-patent-expiry payments "so long as tied to a non-patent right"). That should be the end of the issue, because the Supply Price is not a patent royalty but instead a payment for the manufacture and supply of goods. The SA states that "the Price of the Product manufactured by [Alkermes] to be charged to Acorda under this Agreement shall be equivalent to eight per cent (8%) of the NSP," which it defines as the "Supply Price." SA, Cl. 9.3. The SA never uses the term "royalty," let alone "patent royalty," to refer to the Supply Price.[8] Thus, no alleged *Brulotte* violation could make the Supply Price unenforceable or give Acorda a claim for restitution/unjust enrichment for such payments.

Third, Acorda's repeated references to the Supply Price as being "overmarket" gives it no help. No one disputes that the Supply Price is greater than the marginal cost of manufacturing the AMPYRA® tablets; it includes a profit to Alkermes. But Acorda is merely paying the negotiated price it agreed to pay, so Acorda has no unjust enrichment claim as matter of law. *See, e.g., Granite Partners, L.P. v. Bear, Stearns & Co. Inc.*, 17 F. Supp. 2d 275, 312 (S.D.N.Y. 1998). While parol evidence should be excluded because the terms are clear, that evidence would show that *Acorda*

[8] The Panel's Summary Judgment Order refers to the 8% variously as a "Supply Price[]" (at 3) and as a "royalty" (at 5). Nothing in that Order, or the summary judgment motions themselves, turned on which characterization is correct, and the Order never characterized the Supply Price as a "patent royalty." Indeed, the agreements' use of different terms—"supply price" versus "royalty"—denotes that the terms have different meanings. *See, e.g., Bausch & Lomb Inc. v. Mimetogen Pharms., Inc.*, 2017 WL 2835250, at *12 (W.D.N.Y. June 30, 2017). Even Acorda conceded it is not a patent royalty. Acorda's Opp. to Alk. Mot. in Lim. at 7-8. Thus, the Panel has not found (and should not find) that the Supply Price is subject to *Brulotte*.

proposed the Supply Price be even higher, and the royalty in the LA be even lower, yet following negotiations, the parties landed on the rates contained in the agreements. Having agreed in 2003 to the price terms in the SA, Acorda cannot claim now that the price is unjust.

Fourth, Acorda cannot show that a *Brulotte* violation as to the 10% royalty in the LA caused any overpayment of the Supply Price warranting restitution. A *Brulotte* violation with respect to the 10% royalty in the LA would not mean that the 8% Supply Price in the SA was improperly elevated, even if (as Acorda argues) the two agreements are linked. Acorda asserts the 10% royalty was "too high" due to a *Brulotte* violation, and it seeks restitution for the resulting (purported) overpayment. Such restitution would not involve refunding any portion of the Supply Price, because the Supply Price would be the same whether the 10% royalty needed to be adjusted or not.

Fifth, a *Brulotte* violation would not cause the SA to terminate, so payments under the SA are not "overpayments" warranting restitution. Acorda may argue the LA has terminated, causing the SA to terminate, but that argument is wrong. The '938 patent's expiration did not cause the LA to terminate; the LA provides it will continue after all relevant patents have expired, *and* the LA was extended for five years prior to the '938 patent's expiration. *Supra* at 1-2. Neither would a *Brulotte* violation cause the LA to terminate; Article 12.4 would deem the royalty amended to 4.25%, curing any violation. A *Brulotte* violation would not render the entire LA unenforceable, much less terminated. *Zila, Inc. v. Tinnell*, 502 F.3d 1014, 1023 (9th Cir. 2007) ("*Brulotte* does not render an entire contract void and unenforceable merely because it includes an invalid licensing agreement."). And *Brulotte* has no impact on the SA, as the SA does not involve patent royalties. Acorda therefore cannot show a (purported) *Brulotte* violation caused the SA to terminate, and thus cannot show a *Brulotte* violation led to Supply Price overpayments warranting a refund.

Finally, the evidence shows that Acorda continues to order and receive AMPYRA® from

Alkermes pursuant to the SA. Acorda's own actions in continuing to operate pursuant to the SA belie any argument it may advance that the SA has terminated.

Acorda cannot offer any competent testimony at trial to controvert these facts. While Acorda witnesses may testify that they "believed" or "understood" the agreements to work differently, any such evidence is improper. The agreements contain integration clauses (LA, Art. 12.17; SA, Cl. 14.10) which preclude the use of extrinsic evidence to alter their clear meaning. Moreover, one party's post-contractual subjective understanding of an agreement is not "probative as an aid to the interpretation of the contract." *Faulkner v. Nat'l Geographic Soc.*, 452 F. Supp. 2d 369, 379 (S.D.N.Y. 2006) (quoting *LaSalle Bank Nat'l Ass'n v. Nomura Asset Cap. Corp.*, 424 F.3d 195, 208 n.10 (2d Cir. 2005)).

Altogether, this evidence supports only one conclusion: even if Acorda could show a *Brulotte* violation, it has no basis for seeking a refund of any Supply Price payments.

IV. RELIEF

The Panel should rule on Alkermes's behalf on all claims, and reject Acorda's request for a refund or declaratory relief changing Acorda's payment obligations to Alkermes going forward.

Alternatively, if the Panel were to find a *Brulotte* violation, the Panel should:

1) Deem the know-how royalty provisions in Articles 5.6.1 and/or 5.6.2 of the LA amended to 4.25% of AMPYRA®'s NSP, curing any violation and maintaining the enforceability of the royalty provision;

2) Limit any refund Alkermes is ordered to pay to the difference between royalties calculated at 10% versus 4.25% for payments for the period July 2020 forward, which is approximately $6.5 million;

3) Order that the 4.25% know-how royalty rate applies going forward;

4) Deny any refund of any portion of any Supply Price payments;

5) Order that the Supply Price remains 8% of AMPYRA®'s NSP going forward; and

6) Deny any other claimed relief from Acorda.

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Respectfully submitted,
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